

**AUG 30 2000**

**510(K) SUMMARY  
(as required by 807.92(c))**

**K002319**

**Submitter of 510(k):** Regulatory & Marketing Services, Inc.  
3234 Ella Lane  
New Port Richey, FL 34665

Phone: 813-645-2855  
Fax: 813-645-2856

**Contact Person:** Art Ward

**Date of Summary:** May 5, 2000

**Trade Name:** Purilens Saline Solution

**Classification Name:** Accessories to Contact Lenses – Cleaning and Wetting Agents

**Predicate Device:** Automatic Liquid Packaging 4 OZ. Sterile Unpreserved Saline  
Solution P850070

**Intended Use:**

Purilens Saline Solution is indicated for the cleaning and disinfecting of contact lenses by means of use in a Purilens Electronic Lens Care System. Lenses may be stored in disinfected solution for a period of 24 hours following the cleaning and disinfecting.

**Description/Comparison:**

Purilens Saline Solution is a sodium chloride liquid which is identical to the predicate device and made by the predicate device manufacturer.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**AUG 30 2000**

Purilens, Inc.  
c/o Mr. Arthur Ward  
Regulatory Consultant  
3234 Ella Lane  
New Port Richey, FL 34665

Re: K002319  
Trade Name: Purilens Saline Solution  
Regulatory Class: II  
Product Code: LPN  
Dated: July 10, 2000  
Received: July 31, 2000

Dear Mr. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

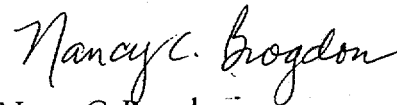
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. Arthur Ward

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "Nancy C. Brogdon".

Nancy C. Brogdon  
Acting Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

510(k) Number (if known): K002319

Device Name: Purilens Saline Solution


**Indications For Use:**

Purilens Saline Solution is indicated for the cleaning and disinfecting of contact lenses by means of use in a Purilens Electronic Lens Care System. Lenses may be stored in disinfected solution for a period of 24 hours following the cleaning and disinfecting.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, Ph.D. 

(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K002319



Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)